

## REMARKS

Claims 1-53 and 65-68 have been canceled. Claims 54-64 and 69-107 are pending and Claims 54 and 58-64 have been rejected. Claims 55-57 and 69-107 have been withdrawn.

### **I. Double Patenting**

The applicant acknowledges this rejection and requests that, in light of the accompanying remarks, the rejection be held in abeyance until allowable subject matter is indicated.

### **II. 35 U.S.C. § 102**

The Examiner rejected claims 54 and 58-64 under 35 U.S.C. § 102(b) as being anticipated by Kohn (U.S. Patent No. 6,365,616). Applicant traverses the rejection for at least the reasons asserted in earlier responses and the reasons set forth below.

Kohn teaches treatment of SLE patients using certain compounds. According to the Examiner, “a portion of SLE patients do in fact have [a] cardiovascular disorder.” Office Action at 3 (emphasis added). The Examiner concludes that Kohn therefore “does in fact teach the inherent treatment of cardiovascular disorder by treatment of SLE.” Office Action at 3.

Applicants respectfully disagree with the Examiner’s conclusion regarding inherent anticipation. Because only 40% of SLE patients dying of active disease have lesions indicative of a cardiovascular disorder, prior art treatments for SLE do not inherently anticipate treatments for cardiovascular disorders. The possibility that a treatment for SLE will also treat a cardiovascular disorder does not legally suffice to show anticipation.

“Inherent anticipation requires that the missing descriptive material is ‘necessarily present,’ *not merely probably or possibly present*, in the prior art.” Rosco, Inc. v. Mirror Lite Co., 304 F.3d 1373, 1380 (Fed. Cir. 2002) (quoting Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1295 (Fed. Cir. 2002)) (emphasis added); see also Mehl/Biophile Int’l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (finding that mere “possibility . . . does not legally suffice to show anticipation. Occasional results are not inherent.” (citation omitted)).

The Federal Circuit’s decision in Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368 (Fed. Cir. 2005), is instructive. In that case, the court considered whether claims to methods of topically applying compositions to skin to treat or prevent sunburn were inherently anticipated by Pereira, a reference teaching topically applying those same compositions to skin to have beneficial effects on the skin. The court distinguished the claims that called for the application of the compositions to skin to *prevent* sunburn from the claims that called for the application of the compositions to *treat* existing sunburn. See id. at 1379.

Because all skin is susceptible to sunburn, the compositions applied to any skin necessarily prevents sunburn, and Pereira anticipated claims related to *prevention* of sunburn. See id.

However, the Federal Circuit noted that not all skin is sunburned, and Pereira’s disclosure of topical application to skin did not necessarily result in application to sunburned skin. Id. The court explained: “Skin sunburn is not analogous to skin surfaces generally. Thus, there is an important distinction between topical application to skin for the purpose of avoiding sunburn, and the much narrower topical application to skin sunburn.” Because Pereira was “silent about any sunburn prevention or treatment benefits, not to mention the mechanisms underlying such uses,” it did not inherently anticipate the claims related to *treatment* of sunburn. Id. The Federal

Circuit explained: “The issue is not . . . whether Pereira’s lotion *if applied* to skin sunburn would inherently treat that damage, but whether Pereira discloses the application of its compound to skin sunburn. It does not.” Id. at 1378.

Similarly, the question here is not whether compounds disclosed in Kohn if administered to a patient having a cardiovascular disorder would inherently treat that disorder, but whether Kohn’s use of the compounds to treat SLE necessarily treated a cardiovascular disorder. It did not. Because 40% of SLE patients have cardiovascular disease, there was a 40% chance that Kohn may have treated someone with cardiovascular disease. A *chance* of treatment is far short of *necessarily* treating. See Mehl/Biophile Int’l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (finding that mere “possibility . . . does not legally suffice to show anticipation. Occasional results are not inherent.” (citation omitted)). In fact, for all that can be told from Kohn, he did not treat anyone with cardiovascular disorders.

The analogy between these facts and those in Perricone is apt. The claims to use of certain compounds to treat sunburn in Perricone were not anticipated by a reference disclosing use of those compounds to benefit skin generally, because not all skin is sunburned. Similarly, the present application’s claims to use of certain compounds to treat a cardiovascular disease are not anticipated by a reference teaching use of those compounds to treat SLE, because not all SLE patients have a cardiovascular disease.

Accordingly, Kohn’s teaching of treatment of SLE with certain compounds is not an inherent treatment of cardiovascular disorders, since most SLE patients do not have cardiovascular disorders.

Kohn also does not render the present claims obvious. Kohn makes no suggestion that the disclosed compounds could be used to treat cardiovascular disorders.

### **CONCLUSION**

In view of the foregoing remarks, Applicant respectfully requests consideration and allowance of the pending claims. Finally, Applicant respectfully requests the courtesy of a phone call in order to resolve any outstanding issues.

### **Authorization of Deposit Account**

The Commissioner is hereby authorized to charge any fees which may be required during the entire pendency of this application, or credit any overpayment, to Deposit Account No. 18-0586. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire pendency of this application.

Respectfully submitted,  
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